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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: EIS-SCHWARTZ=2B ✓

In re Application of:	)	Conf. No.:
	)	
Michel EISENBACH-SCHWARTZ et al)	)	Art Unit:
	)	
Appln. No.: 10819653	)	Examiner:
	)	
Filed:	)	Washington, D.C.
	)	
For: A METHOD FOR REDUCING	)	July 30, 2004
NEURONAL DEGENERATION SO	)	
AS TO AMELIORATE THE	)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window, Mail Stop Amendment  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office

action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

*(Check one of the boxes "i" and "ii" below:)*

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check (check no. \_\_\_\_\_) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either

*(Check one of the boxes "a" and "b" below)*

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

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☒ 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

*(check boxes A and/or B and fill in blanks, if appropriate)*

☐ A. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

[X] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

09/314,161 May 19, 1999

09/893,348 October 31, 2001

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

[ ] 3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with §1.98(a)(3), Applicant(s) states:

[ ] An English translation of each document \_\_\_\_\_ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached \_\_\_\_\_ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

*(insert concise explanation of relevance)*

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

[ ] A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

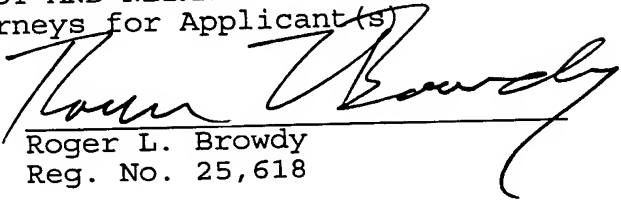
[ ] 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK  
Attorneys for Applicant(s)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1. of 8.

**Complete if Known**

Application Number	
Filing Date	
First Named Inventor	Michal EISENBACH-SCHWARTZ
Group Art Unit	
Examiner Name	
Attorney Docket Number	EIS-SCHWARTZ=2B

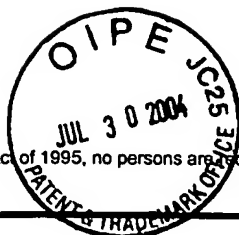
**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US 5,250,414	10-05-1993	Schwab et al	
	AB	US 5,684,133	11-04-1997	Schwab et al	
	AC	US 5,114,721	05-19-1992	Cohen et al	
	AD	US 5,633,426	05-27-1997	Namikawa et al	
	AE	US 5,858,364	01-12-1999	Weiner et al	
	AF	US 6,319,892	11-20-2001	Gold et al	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>4</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	AG	WO 01/36631 A1	05-25-2001	Smithkline Beecham Plc		
	AH	WO 00/60083 A1	10-12-2000	Chiron Corporation		
	AI	WO 00/31235 A1/3	06-02-2000	Schwab et al		
	AJ	WO 99/53945	10-28-1999	Braun et al		
	AK	WO 99/12966	03-18-1999	Linnington et al		
	AL	WO 97/35879	10-02-1997	Immologic Pharma Corp		
	AM	WO 97/14427	04-24-1997	Haglid Kenneth G		
	AN	WO 96/16085 A1	05-30-1996	Neurocrine Biosciences Inc. & Stanford Univ Medical Center		
	AO	WO 96/12737	05-02-1996	Immologic Pharma Corp		
	AP	WO 95/27500	10-19-1995	Brigham & Womens Hospital		
	AQ	WO 95/22344	08-24-1995	Braun et al		
	AR	WO 93/21222	10-28-1993	Ariel et al		
	AS	WO 93/00427 A2	01-07-1993	Erziehungsdirektion Cant. Zurich		
	AT	WO 91/01746	02-21-1991	Childrens Medical Center		

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Sheet .2

of 8.

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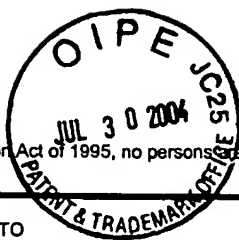
**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AU	BECKER, et al, "Immunologic Tolerance to Myelin Basic Protein Decreases Stroke Size After Transient Focal Cerebral Ischemia", <u>Proc Natl Acad Sci USA</u> 94(20):10873-10878 (1997)	
	AV	BEN-NUN, et al., "The Rapid Isolation of Clonable Antigen-specific T Lymphocyte Lines Capable of Mediating Autoimmune Encephalomyelitis," <u>Eur J Immunol.</u> , 11:195-199, (1981)	
	AW	BERKOW, et al (Eds), <u>The Merck Manual of Diagnosis and Therapy</u> 16 <sup>th</sup> Ed., Merck Research Laboratories, Rahway, NJ, pp. 110, 111, 412, 413, 1452-1459, 1488-1490, 1510, 1511, and 1518-1523 (1992)	
	AX	BRADBURY, et al, "NT-3, but not BDNF, Prevents Atrophy and Death of Axotomized Spinal Cord Projection Neurons", <u>Eur J Neurosci</u> ;10(10):3058-3068 (1998)	
	AY	BRITTIS, et al., "Nogo Domains and a Nogo Receptor: Implications for Axon Regeneration", <u>Neuron</u> , 30(1):11-14 (2001)	
	AZ	BROD, et al, "Autologous T-T Cell Activation Mediated by Cell Adhesion Molecules", <u>FASEB J</u> 3(3):A514 (1989)	
	BA	BROSAMLE, et al., "Regeneration of Lesioned Corticospinal Tract Fibers in the Adult Rat Induced by a Recombinant, Humanized IN-1 Antibody Fragment", <u>J Neurosci</u> , 20(21):8061-8068, (2000)	
	BB	BURNS, et al., "Isolation of Myelin Basic Protein-Reactive T-Cell Lines from Normal Human Blood", <u>Cellular Immunology</u> , 81:435-440 (1983)	
	BC	CHEN, et al., "Regulatory T Cell Clones Induced by Oral Tolerance: Suppression of Autoimmune Encephalomyelitis", <u>SCIENCE</u> , 265: 1237-1240 (1994)	
	BD	CHEN, et al, "Nogo-A is a Myelin-Associated Neurite Outgrowth Inhibitor and an Antigen for Monoclonal Antibody IN-1", <u>Nature</u> 403(6768):434-439 (2000)	
	BE	COHEN, "The Cognitive Principle Challenges Clonal Selection", <u>Immunology Today</u> , 13(11):441-444, (1992)	
	BF	COHEN, et al, "Autoimmune Maintenance and Neuroprotection of the Central Nervous System", <u>J Neuroimmunol</u> ; 100(1-2):111-114 (1999)	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



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Sheet 3 of .8

**Complete if Known**

Application Number	
Filing Date	On even date herewith
First Named Inventor	Michal EISENBACH-SCHWARTZ
Group Art Unit	
Examiner Name	
Attorney Docket Number	EIS-SCHWARTZ=2B

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	BG	ENOCH, et al, "Different Functional Changes Recorded In Open Angle Glaucoma and Anterior Ischemic Optic Neuropathy", <u>Doc Ophthalmol</u> 50(1):169-184 (1980)	
	BH	FADEN, "Experimental Neurobiology of Central Nervous System Trauma" <u>Critical Reviews in Neurobiology</u> 7(3/4):175-186 (1993)	
	BI	FEIGIN, et al, "Recent advances in Huntington's disease: implication for experimental therapeutics", <u>Curr Opin Neurol</u> 15:483-48 (2002)	
	BJ	FOURNIER, et al, "Identification of a receptor mediating Nogo-66 inhibition of axonal regeneration", <u>Nature</u> 409(6818):341-346 (2001)	
	BK	GEORGE, et al, "Axotomy-induced Axonal Degeneration is Mediated by Calcium Influx through Ion-Specific Channels", <u>J Neurosci</u> 15(10):6445-6452 (1995)	
	BL	GRANDPRE, et al., "Identification of the Nogo Inhibitor of Axon Regeneration as a Reticulon Protein", <u>Nature</u> 403(6768):439-444 (2000)	
	BM	GRANDPRE, et al., "Nogo-66 Receptor Antagonist Peptide Promotes Axonal Regeneration." <u>Nature</u> 417(6888):547-551 (2002)	
	BN	HALLIDAY, et al, "Alzheimer's Disease and Inflammation: A Review of Cellular and Therapeutic Mechanisms", <u>Clin Exp Pharmacol Physiol</u> 27:1-8, 2000.	
	BO	HAUBEN, et al, "Autoimmune T Cells As Potential Neuroprotective Therapy For Spinal Cord Injury", <u>Lancet</u> 355(9200):286-287 (2000)	
	BP	HAUBEN, et al, "Passive or active immunization with myelin basic protein promotes recovery from spinal cord contusion", <u>J Neurosci</u> , 20(17):6421-6430 (2000)	
	BQ	HAUBEN, et al, "Vaccination with a Nogo-A-Derived Peptide after Incomplete Spinal-cord Injury Promotes Recovery Via a T-Cell-Mediated Neuroprotective Response: Comparison with other Myelin Antigens", <u>Proc Natl Acad Sci USA</u> 98(26): 15173-15178 (2001)	
	BR	HAY RJ, "Human Cells and Cell Cultures: Availability, Authentication and Future Prospects", <u>Hum Cell</u> 9(3):143-152 (1996)	

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SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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First Named Inventor	Michal EISENBACH-SCHWARTZ
Group Art Unit	
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Attorney Docket Number	EIS-SCHWARTZ=2B

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

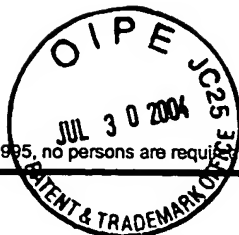
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	BS	HICKEY, et al., "T-Lymphocyte Entry into the Central Nervous System", <u>Journal of Neuroscience Research</u> 28:254-260 (1991)	
	BT	HIRSCHBERG, et al., "Accumulation of Passively Transferred Primed T cells Independently of their Antigen Specificity Following Central Nervous System Trauma", <u>Journal of Neuroimmunology</u> 89:88-96 (1998)	
	BU	HOVDA, et al., "Diffuse Prolonged Depression of Cerebral Oxidative Metabolism following Concussive Brain Injury in the Rat: A Cytochrome Oxidase Histochemistry Study", <u>Brain Research</u> 567:1-10 (1991)	
	BV	HUBER, et al, "Nogo-A, a potent inhibitor of neurite outgrowth and regeneration", <u>Biol Chem</u> 381(5-6):407-419 (2000)	
	BW	HUBER, et al, "Patterns of Nogo Mma and Protein Expression in the Developing And Adult Rat and after CNS Lesions", <u>J Neurosci</u> 22(9):3553-3567 (2002)	
	BX	JACKOWSKI A, "Neural Injury Repair: Hope for the Future as Barriers to Effective CNS Regeneration Become Clearer", <u>Br J Neurosurg</u> 9(3):303-317 (1995)	
	BY	JANEWAY, Jr., "The Immune System Evolved to Discriminate Infectious Nonself from Noninfectious Self", <u>Immunology Today</u> 13(1):11-16, (1992)	
	BZ	KANDEL et al (Eds.), <u>Principles of Neural Science</u> Elsevier Science Publishing Co., Inc. (New York, NY), pp. 977-982	
	CA	KERSCHENSTEINER et al., "Activated Human T Cells, B Cells, and Monocytes Produce Brain-derived Neurotropic Factor In Vitro and in Inflammatory Brain Lesions: A Neuroprotective Role of Inflammation", <u>J. Exp. Med.</u> 189(5):865-870, (1999)	
	CB	KRAMER et al., "Gene transfer through the blood-nerve barrier: NGF-engineered neuritogenic T Lymphocytes attenuate experimental autoimmune neuritis", <u>Nature Medicine</u> , 1(11):1162-1166 (1995)	
	CC	LAZAROV et al., "Transplantation of activated macrophages results in partial recovery of paraplegic rats", <u>Nature Medicine</u> , 4(7):814-821 (1998)	
	CD	Li et al, "β-Endorphin omission analogs: dissociation of immunoreactivity from other biological activities", <u>Proc Natl Acad Sci USA</u> 77(6):3211-3214 (1980)	

Examiner  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 5 of 8.

**Complete if Known**

Application Number	
Filing Date	On even date herewith
First Named Inventor	Michal EISENBACH-SCHWARTZ
Group Art Unit	
Examiner Name	
Attorney Docket Number	EIS-SCHWARTZ=2B

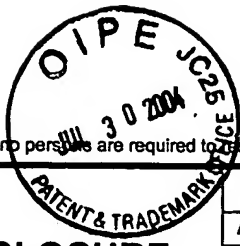
**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	CE	LIU et al, "Hydroxyl Radicals Generated In Vivo Kill Neurons in the Rat Spinal Cord: Electrophysiological, Histological, and Neurochemical Results", <u>Journal of Neurochemistry</u> , 62(1):37-44 (1994)	
	CF	LIUZZI, et al, "Peripheral Nerve Regeneration", <u>Neurosurg Clin N Am</u> 2(1):31-42 (1991)	
	CG	LOHSE, et al, "Control of Experimental Autoimmune Encephalomyelitis by T Cells Responding to Activated T Cells", <u>Science</u> 244:820-822 (1989)	
	CH	LOHSE, et al, "Inhibition of the Mixed Lymphocyte Reaction by T Cell Vaccination", <u>Eur J Immunol</u> 20:2521-2524 (1990)	
	CI	LOHSE, et al, "Induction of the Anti-Ergotypic Response", <u>International Immunology</u> 4(5):533-539 (1993)	
	CJ	MARTIN, et al, "Gene Specificity and HLS Restriction of Myelin Basic Protein Specific Cytotoxic T Cell Lines from Multiple Sclerosis Patients and Healthy Individuals" <u>The Journal of Immunology</u> , 145(2):540-548 (1990)	
	CK	MERKLER, et al, "Locomotor Recovery in Spinal Cord-injured Rats Treated with an Antibody Neutralizing the Myelin-associated Neurite Growth Inhibitor Nogo-A," <u>J. Neurosci.</u> 21(10):3665-3673 (2001)	
	CL	MOAELEM et al, "Autoimmune T Cells Protect Neurons from Secondary Degeneration after Central Nervous System Axotomy", <u>Nature Medicine</u> 5(1):49-55 (1999)	
	CM	MOALEM et al, "Autoimmune T cells Retard the Loss of Function in Injured Rat Optic Nerves", <u>J Neuroimmunol</u> 106(1-2):189-197 (2000)	
	CN	MOR et al, "Pathogenicity of T Cells Responsive to Diverse Cryptic Epitopes of Myelin Basic Protein in the Lewis Rat," <u>The Journal of Immunology</u> , 155(7):3693-3699 (1995)	
	CO	MORRIS et al, "The Consortium to Establish a Registry for Alzheimer's Disease (CERAD). Part I. Clinical and Neuropsychological Assessment of Alzheimer's Disease", <u>Neurology</u> 39(9):1159-1165 (1989)	
	CP	OTA et al, "T-cell Recognition of an Immunodominant Myelin Basic Protein Epitope in Multiple Sclerosis," <u>NATURE</u> , 346:183-187 (1990)	

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Sheet 6 of 8.

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	CQ	PAN, et al, "Tumor Necrosis Factor-alpha: A Neuromodulator in the CNS", <u>Neurosci Biobehav Rev</u> 21(5):603-613 (1997)	
	CR	PETTE, et al., "Myelin in Autoreactivity in Multiple Sclerosis: Recognition of Myelin Basic Protein in the Context of HLA-DR2 Products by T Lymphocytes of Multiple-Sclerosis Patients and Healthy Donors", <u>Proc. Natl. Acad. Sci. USA</u> 87:7968-7972(1990)	
	CS	PETROVICH, et al, "Pentoxifylline Suppression of TNF- $\alpha$ Mediated Axonal Degeneration in the Rabbit Optic Nerve," <u>Neurol Res</u> 19(5):551-554 (1997)	
	CT	PLATA SALAMAN C, "Epidermal Growth Factor and the Nervous System", <u>Peptides</u> 12(3):653-663 (1991)	
	CU	POPOVICH, et al, "Cellular Inflammatory Response After Spinal Cord Injury in Sprague-Dawley and Lewis Rats" <u>The Journal of Comparative Neurology</u> , 377:443-464, (1997)	
	CV	POPOVICH, et al, "Concepts of Autoimmunity Following Spinal Cord Injury: Possible Roles for T Lymphocytes in the Traumatized Central Nervous System", <u>Journal of Neuroscience Research</u> , 45:349-363, (1996)	
	CW	POSER CM, "The Role of Trauma in the Pathogenesis of Multiple Sclerosis: A Review," <u>Clin Neurol Neurosurg</u> 96(2):103-110 (1994)	
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	CY	RAPALINO, et al, "Implantation of Stimulated Homologous Macrophages Results in Partial Recovery of Paraplegic Rats," <u>Nature Medicine</u> , 4(7):814-821 (1998)	
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	DA	SCHWAB, et al, "Degeneration and Regeneration of Axons in the Lesioned Spinal Cord," <u>Physiol Rev.</u> , 76(2):319-370, (1996)	
	DB	SCHWARTZ, J, "Synthesis and Trafficking of Neuronal Proteins," <u>Principles of Neural Science</u> , Connecticut: Appleton and Lange, 1991, pages 49-65; pg 264-265	

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Application Number	
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Group Art Unit	
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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	DC	SKOLNICK, et al, "From Genes to Protein Structure and Function: Novel Applications of Computational Approaches in the Genomic Era", <u>Trends Biotechnol</u> 18(1):34-39 (2000)	
	DD	STEECE-COLLIER, et al, "Etiology of Parkinson's Disease: Genetics and Environment Revisited," <u>Proc Natl Acad Sci USA</u> 99(22):13972-13974 (2002)	
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	DG	TANABE, et al, "Diversity and pattern in the developing spinal cord", <u>SCIENCE</u> 274(5290):1115-1123 (1996)	
	DH	WANG, et al, "Pathogenesis of axonal degeneration: parallels between Wallerian degeneration and vincristine neuropathy", <u>J Neuropathol Exp Neurol</u> 59(7):599-606 (2000)	
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	DN	YÜCEL, et al, "Histomorphometric Analysis of Optic Nerve Changes in Experimental Glaucoma", <u>J Glaucoma</u> 8(1):38-45 (1999)	

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